(For committee use only)

RRC Log# _____

PRIMARY REVIEWER _____

RESEARCH PROPOSAL APPLICATION
SUBMISSION TO RESEARCH REVIEW COMMITTEE

If you require further assistance in completing this form or in your dealings with the Research Review Committee (RRC), contact Erin G. Brown, Chairperson, (617) 624-7517. The Principal Investigator must initial and date the bottom of every page. Attach additional pages if necessary. Please mail a complete copy of the Application to DDS Research and Review Committee, c/o Erin G. Brown, Department of Developmental Services, 40 Broad Street, 4th Floor, Boston, MA 02109 or send Application & materials via email to Erin.Brown@mass.gov

SECTION A

1. Title of Study:

2a. Principal Investigator (name/address/telephone #)

2b. Co-investigator (s) and affiliation:

3. Expected Starting Date:__Upon approval_____

4. Expected Completion Date:_____

5. Location(s) where the study will be conducted?

Judge Rotenberg Educational Center (JRC)
250 Turnpike St
Canton, MA 02021

6. Has your study or a similar one been previously reviewed by the Department of Developmental Services or by the Department of Mental Health?
☐Yes ☐No
If yes, please describe the circumstances.

7. Has the study or a similar one been rejected by any review group or committee? ☐Yes ☐No If yes, please provide details.

SECTION B

Summary of the Research Protocol

8. List the purposes and objectives of the research.

9. Describe the research method(s) and procedure(s) to be used.

There are no experimental activities. The project involves only retrospective analysis of historical data collected prior to date of approval to include treatment plans, behavior frequency charts, and associated existing records.

115 CMR 10.02 - Research means a systematic investigation designed to develop or contribute to generalizable knowledge and involving access to human subjects or private information, but shall not include: (a) *any nonexperimental activity, such as diagnosis, preventive treatment and therapy, designed solely to enhance the well being of a particular individual.*

10a. What are the direct benefits of the research to the participant? If there is no direct benefit knowledge that might benefit persons with intellectual disabilities or their families or the field of intellectual disabilities.

There are no direct benefits to the participants of this study. This study will result in knowledge that will be beneficial to people with developmental and intellectual disabilities, as well as their families, caregivers, and clinical teams. This study has the potential to describe the efficacy and efficiency of **[insert procedures]**

10b Why should persons with intellectual disabilities participate in the study?

The information derived from this study could potentially help a small group of people with intellectual disabilities who exhibit extraordinarily severe problem behaviors including self-injury and aggression.

10c. Can research questions be answered through the use of persons without intellectual disabilities? If no, please explain.

No. A significant portion of individuals who received treatment at JRC have been assigned a diagnosis of intellectual disability and we wish to show the effects across a range of people with various diagnoses and levels of functioning.

SECTION C

Study Population

11. Number of participants _____

12. Age range of participations_____

13. Source of participants: Judge Rotenberg Educational Center

14. List all criteria for including participants in the study.

15. List all criteria for excluding individuals from the study.

16. To your knowledge, will any participant also be participating in other research studies? ☒Yes ☐No
If yes, please describe.

Some participants may be participating in other research projects at JRC that also involve access to only historical data collected prior to date of approval.

17. *Describe how you will recruit participants. Recruitment should address how conflict of interest, preliminary access to person health information and freedom from coercion will be addressed.

A. Direct person-to-person solicitation (participant, family, guardian, provider) ☐
B. Telephone ☐
C. Letter ☐
D. Notices ☐
E. Electronic ☐
F. Video ☐
G. Audio ☐
H. Other (explain) ☐

***If the participants are to be recruited under A & B, please include an outline of the oral presentation. For items C, D, and E please submit verbatim copies--e.g., letter, notices, advertisements.**

There is no recruitment process as the study involves only historical data collected prior to date of approval.

18. Describe the type of private information that will be sought?

Treatment plans, behavior frequency charts, demographic information, and associated existing historical records.

19. Describe how the research may affect the care or treatment of the participant <u>during</u> the research and <u>after</u> the research has ended.

No effect on care or treatment of the participants in any way.

20a. What rewards, remuneration, or other incentives will be used to recruit participants?

None.

20b. Describe any foreseeable cost (s) to the individual as a result of participating in the

research (e.g., lost wages, travel and parking expenses, lunch, etc.), and any compensation or reimbursement that will be offered to the participant to offset such cost(s).

There will be no cost to the individual.

21. Attach a budget showing the project expenditures and sources and amounts of funding for the project.

This project will be conducted in-house and has no budget.

22. Do you intend to rely on the Department of Developmental Services or provider resources for assistance in conducting the research, collecting data, or providing private information?

☐ **Yes** ☒ **No**

If yes, describe.

SECTION D

Interventions/Measurements Solely for Research Purposes

23. Will blood samples be required? If yes, describe. ☐ **Yes** ☒ **No**

Specify the important features of the blood collection, including the volume of research blood obtained in each collection, along with the frequency and duration of the collection (e.g., 10 ml at noon and 8 p.m., one day every two weeks for a six-month period).

Is it known or anticipated that any participant will also have blood drawn for other purposes during the study period? ☐ **Yes** ☐ **No**

24. Please indicate any of the following you propose to use:

- **a. Educational Tests** ☐
- **b. Questionnaires** ☐
- **c. Psychological Tests** ☐
- **d. Educational Materials (curriculum, books)** ☐
- **e. Interview** ☐
- **f. Diary** ☐

None of the above.

25. Will the study involve the use of drugs? ☐ **Yes** ☒ **No**

If yes, explain.

SECTION E

Confidentiality--Privacy--Coercion

26. Does this activity utilize data collected for other purposes? ☒Yes ☐No (e.g., hospital records, electronic, video, audio)

a. If yes, please specify the source of the data to be utilized and how the data will be retrieved and reviewed.

Data will be retrieved from a charting system used at JRC and from the historical records on file at the JRC. The treatment history (before and after admission to JRC) will be summarized without using any identifying information.

b. Could any of the recorded data contain personal or sensitive information? ☒Yes ☐No If yes, how do you propose to code and where will you maintain confidentiality of the data?

All private information will be maintained, in original form, at JRC and in accordance with state and federal regulatory requirements.

27. Describe the safeguards that will be implemented to maintain confidentiality of the private information obtained during the research. This must include safeguards for any electronic transmission and storage, audio, or videotaping, and the like.

All electronic research information will be maintained in a dedicated folder, on a computer at JRC which is password protected, and located in a locked office. Only investigators will access the data. Electronic research products will be disposed in accordance with Office for Human Research Protections (OHRP) regulatory guidelines.

28. Describe the manner of disposal of the private information at the termination of the study. This must include safeguards for any electronic transmission or recording, audio, or videotaping, and the like.

All electronic information will be maintained in a dedicated folder, on a computer at JRC which is password protected, and located in a locked office. Only investigators will access the data. Electronic research products will be disposed in accordance with OHRP regulatory guidelines.

29. Aside from possible loss of confidentiality, could any part of this activity be seen as invading the privacy of the participants of this study? ☐Yes ☒NO If yes, explain and describe proposed safeguards.

30. Does any part of this activity have the potential for coercion of the participant? ☐Yes ☒No. If yes, explain and describe proposed safeguards.

31a. Describe the type of final product to be produced, its intended use and the manner of dissemination or publication.

The final products will be presentations and papers submitted to professional and academic

conferences and journals, respectively. Conferences may publish research abstracts electronically and in print. Journals may disseminate articles electronically and in print.

31b. Do you or others intend to establish copyright, patents, or any other rights to the product? ☐**Yes** ☒**No**

If yes, identify the organization or persons in whom such rights are vested.

SECTION F

Risks: Physiological or Psychological

32a. Is there a foreseeable risk of physical injury resulting from participation in the research? ☐**Yes** ☒**No**

If yes, describe the likelihood and seriousness of the risk.

****Note: Include in your discussion an explanation of why the risks identified under 32(a-c) should be considered reasonable in relation to the anticipated benefits to participants and in relation to the importance of the knowledge that may reasonably be expected to result from the research.**

32b. Aside from possible loss of confidentiality, is there a foreseeable risk of psychological injury resulting from participation in the research? ☐**Yes** ☒**No**

If yes, describe the likelihood and seriousness of the risk.

32c. List any other foreseeable risk to the participant (e.g. social, economic, legal), and if applicable, provide a full discussion of the likelihood and potential and seriousness of the risk (s). (See ** on page 7)

None

SECTION G

Informed Consent

A written informed consent from the subject or from a legally responsible representative of the subject is normally required from research participants. The proposed consent form should be included with the materials submitted to the RRC. The consent form must include all the points listed on the attached checklist (RRC Form #2).

33. Describe how it will be determined that individuals you are seeking to include in the study have the capacity to consent to participate. For example, researchers may rely on Human Rights Committees, institutional staff, clinicians who know the individual, or a guardian, if one is established.

The Department of Developmental Services regulation 115 CMR 10.07(6) suggests that if the committee finds the research is only a study of historical records and plans are presented to

protect confidentiality, the regulations 115 CMR 10.07(1) through 10.07(5) do not apply.

34. If necessary, how will guardians be contacted?

By phone, email, and/or physical mail.

35. If you do not propose to obtain consent, please provide your rationale.

The Department of Developmental Services regulation 115 CMR 10.07(6) suggests that if the committee finds the research is only a study of historical records and plans are presented to protect confidentiality, the regulations 115 CMR 10.07(1) through 10.07(5) do not apply.

The research consists of the study of historical records **[insert time frame]** and therefore should not require individual consent. In this proposal we also present plans to protect confidentiality as outlined in Section E.

36. **Describe the manner in which informed consent will be obtained (who, how, when).**

If necessary, JRC staff will send letters and contact participants by phone under the direction of the researchers. This process will begin if the project is approved and consent is required.

37. Audio/video taping and the like is considered personal health information. Will these types of information be utilized? If so, which?

None.

INVESTIGATOR'S STATEMENT:

I UNDERSTAND THAT I AM RESPONSIBLE FOR THE ACCURACY OF THE STATEMENTS MADE IN THIS PROTOCOL AND FOR THE CONDUCT OF THE RESEARCH.

_____ _____

Principal Investigator **Date**